

Remarks

Claims 136-172 are pending in the subject application. By this Amendment, Applicants have canceled claim 157, amended claims 136, 152-155 and 168-172 and added new claims 173-177. Support for the new claims can be found throughout the subject specification and in the claims as originally filed (see, for example, page 12, line 31 and page 18, lines 26-33). Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 136-156 and 158-177 are currently before the Examiner; claims 136, 139-141, 144-147, 149-155, 158, 160-163 and 165-177 read on the elected invention. Favorable consideration of the pending claims is respectfully requested.

Applicants note that the Office Action indicates that a priority date of July 28, 2000 has been awarded for the invention of claims 136, 139-141, 144-147, 149-155, 158, 160-163 and 165-172. The Office Action contends that parent application 09/540,462 and 60/127,755 fail to provide adequate support under 35 U.S.C. § 112 for the full scope of the claims. Particularly, the Patent Office argues that the term "robotics" is not specifically recited within the '462 application nor is any guidance provided that would reasonably lead a person of skill in the art to automation that "resembles" a human being. The Office Action further contends that a definition of the terms "robot" and "robotics" requires that the mechanical apparatus resemble a human being. Applicants respectfully submit that the holding that the previously presented claims are entitled only to a priority date of July 28, 2000 is incorrect.

In general, the test for determining compliance with the written description requirement of 35 U.S.C. § 112 is whether the disclosure of the application as originally filed reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claim language under consideration. See *Wang Laboratories Inc. v. Toshiba Corp.*, 993 F.2d 858, 865, 26 USPQ2d 1767, 1774 (Fed. Cir. 1993); *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1556, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991); see also *In re Kaslow*, 707 F.2d 1366, 1375, 217 U.S.P.Q. 1089, 1096 (Fed. Cir. 1983). Absent an express intent to impart a novel meaning to a claim term, the words take on the

ordinary and customary meanings attributed to them by those of ordinary skill in the art (*see Int'l Rectifier Corp. v. LXYS Corp.*, 361 F.3d 1363, 1369, 70 U.S.P.Q.2d 1209 (Fed. Cir. 2004); *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1298, 67 U.S.P.Q.2d 1132 (Fed. Cir. 2003)) and to determine the ordinary and customary meaning of a claim term, one may review sources including the claims themselves (*see Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357 (Fed. Cir. 1999); dictionaries and treatises, *Texas Digital Sys. v. Telegenix, Inc.*, 308 F.3d 1193, 1202, 64 U.S.P.Q.2d 1812 (Fed. Cir. 2002); and the written description, drawings, and prosecution history, *see, e.g., DeMarini Sports, Inc. v. Worth, Inc.*, 239 F.3d 1314, 1324, 57 U.S.P.Q.2d 1889 (Fed. Cir. 2001). In every case, the specification must be examined in every case to determine which of the possible dictionary meanings is consistent with the use of the claim term in the context of the claims and the written description and to determine if the presumption of ordinary and customary meaning is rebutted. *See Ferguson Beauregard v. Mega Sys., LLC*, 350 F.3d 1327, 1338-39, 69 U.S.P.Q.2d 1001 (Fed. Cir. 2003); *Rentshaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250, 48 U.S.P.Q.2d 1117 (Fed. Cir. 1988).

In view of this guidance provided by the courts, Applicants respectfully submit that the claims find support in the disclosure of the '462 application. For example, the same dictionary cited by the Patent Office in the Office Action of April 7, 2005 provides a definition of the term "robot" that is more consistent with the use of the claim term in view of the written description of '462 application. Definition "3." (a copy of which is attached hereto for the convenience of the Examiner) indicates that a robot is "3. A machine or device that works automatically or by remote control". Applicants respectfully submit that this definition is more consistent with the use of the claim term in view of the written description of the '462 application than is the definition advanced by the Patent Office. Applicants further submit that one skilled in the art, considering appellants' disclosure as a whole, would not envision the definition of "robot" or "robotics" advanced by the Patent Office; rather, in view of the specification of the instant application and the '462 application (and recognizing that the claimed subject matter does not need to be described *in haec verba* in the specification in order for the specification to satisfy the written description requirement), it is submitted that one skilled in the art would have recognized that the "automated robotics system"

recited in the claims was a system that worked automatically as discussed within the specification of the '462 application at page 20, line 8 through page 23, line 7. Accordingly, Applicants respectfully submit that the claims are entitled to the priority date of the '462 application. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested in view of the arguments advanced herein and the deletion of the term within the claims.

Claims 136, 139-141, 144-147, 149-155, 158, 160-163 and 165-172 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. The Office Action has rejected claims 136 and 155 on the basis that it is not clear how "'automated' systems differ from 'automated robotic'" systems. Applicants respectfully submit that this issue is moot in view of the deletion of the term "robotic" in the claims. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §112, second paragraph, is respectfully requested.

The Office Action has also rejected claims 151-154 and 167-170 on the basis that the terms optimize and optimized are relative terms that renders the claims indefinite. Applicants respectfully submit that this issue is moot in view of the amendments made to claims 152-154 and 168-170. Turning to this issue as it has been applied to claims 151 and 167, it is respectfully submitted that the term "optimized" is definite. The specification indicates, at page 3, lines 25-33, that the instant invention provides the ability to optimize any particular desired property, result or both property and result of a pharmaceutical formulation. The Webster's II New Riverside Dictionary (Soukhanov *et al.*, Eds., 1988, The Riverside Publishing Co., Boston) defines "optimize" as "to improve or develop as far as possible". Thus, it would be clear to one skilled in the art that the term "optimize" or "optimized", as used herein, relates to formulations having improved properties, results or both properties and results. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §112, second paragraph, is respectfully requested.

The Office Action has also rejected claims 171-172 on the basis that the phrase "said at least three excipients" lacks antecedent basis in the claims from which claims 171-172 depend.

Applicants have amended the claims to address this issue and believe that the rejection is now moot. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §112, second paragraph, is respectfully requested.

Claims 136, 139-141, 144-147, 149-155, 158, 160-163 and 165-172 are rejected under 35 U.S.C. §102(e) as being anticipated by Levinson *et al.* (WO 01/51919). Applicants respectfully submit that WO 01/51919 is not prior art against the presently claimed invention. Applicants respectfully submit that WO 01/51919 fails to teach an interaction that corresponds to increased solubility. Indeed, the reference is drawn to crystallizing compounds out of solution (decreasing the solubility of the compound), not increasing the solubility of a component-in-common. As the cited reference fails to teach "increased solubility" of a component-in-common, it is respectfully submitted that the cited reference fails to anticipate the claimed invention. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §102(e) is respectfully requested.

Claims 136, 139-141, 144-147, 149-151, 155, 158, 160-163, 165-168 and 171-172 are rejected under 35 U.S.C. §103(a) as being unpatentable over Ferris (U.S. Patent No. 4,808,705), Mere *et al.* (Mere, L. *et al.* August 1999 DDT, 4(8), 363-369) and Promega Inc. (1996 Neural Notes, 11(3), 15). Applicants respectfully submit that the cited combination of references fails to render the claimed invention obvious. As the Patent Office is aware, each and every limitation of the claimed invention must be taught or suggested by the prior art in order to establish a *prima facie* case of obviousness for a particular invention (*In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974)). It is respectfully submitted that the cited combination of references fails to meet this requirement. For example, the cited references fail to teach: 1) the use UV spectrophotometers for the analysis step; 2) liquid paclitaxel (taxol) as the component-in-common; or increased solubility of the component-in-common as the interaction that is identified in the steps of the method. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a) is respectfully requested as the rejection fails to raise a *prima facie* case of obviousness for the claimed invention.

Claims 136, 139-141, 144-147, 149-155, 158, 160-163 and 165-172 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 180-304 of copending Application No. 09/756,092 (Pub. No. US 2002/0048610) referred to herein as '092 in view of Levinson *et al.* (WO 01/51919) and/or Merritt (Merritt, A.T. 1998, DDT, 3(11), 505-510). Additionally, claims 36, 139-141, 144-147, 149-155, 158, 160-163 and 165-172 are also provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 170-178 (especially claims 174-178) of copending Application No. 10/372,524 (US 2003/0162226) (referred to herein as '524) in view of Levinson *et al.* (WO 01/51919) and/or Merritt (Merritt, A.T. 1998, DDT, 3(11), 505-510). Applicants respectfully traverse.

A double patenting rejection of the obviousness-type is "analogous to [a failure to meet] the nonobviousness requirement of 35 U.S.C. § 103" except that the patent principally underlying the double patenting rejection is not considered prior art. *In re Braithwaite*, 379 F.2d 594, 154 U.S.P.Q. 29 (C.C.P.A. 1967). Therefore, any analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of an obviousness determination under 35 U.S.C. §103.. *In re Braat*, 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir. 1991); *In re Longi*, 759 F.2d 887, 225 U.S.P.Q. 645 (Fed. Cir. 1985). In the case of the currently pending claims, it is respectfully submitted that the combination of cited documents fails to render the claims obvious. The claims of the '524 application and the '092 application are directed to methods of crystallization. In these methods, a component-in-common is precipitated out of solution by a combination of excipients. These methods contrast with the currently claimed invention in which methods detect an interaction or a synergistic interaction between components of the sample formulations, said interaction being increased solubility of the component-in-common. The teachings of Levinson *et al.* and/or Merritt *et al.* fail to remedy this defect in the claims of the '524 and '092 applications. Accordingly, it is respectfully submitted that the current claims are not obvious over the claims of the cited patent applications and withdrawal of the double patenting rejection is respectfully requested.

Applicants note that the rejections of record do not appear to address the invention elected in the response of November 10, 2004. As indicated in the Restriction Requirement dated August 11, 2004, Applicants are required to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable (see paragraph 7). Applicants, accordingly, elected the following species for examination on the merits:

- a) as the component-in-common: liquid paclitaxel, an "active" component-in-common which is a therapeutic pharmaceutical compound;
- b) as the additional component: polyethylene glycol as an excipient/solubilizing agent);
- c) as the species of analysis: UV spectrophotometer analysis;
- d) as the species of property for the generation of a data sheet: solubility;
- e) as the species of interaction: increased solubility of the component-in-common;
- f) as the species of input: "liquid"
- g) as the species of data mining software: SPOTFIRE and the algorithm(s) provided in the software package; and
- h) as the species of automated robotics system: TECAN liquid pipetting systems.

Should the Patent Office issue new grounds of rejection to address the invention elected in the response of November 10, 2005 in the next Office Action, it is respectfully requested that the Office Action be made non-final.

It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position. Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including

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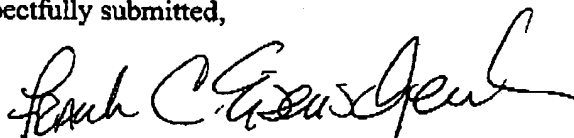
any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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Attachment: Copies of Definitions for "Optimize" and "Robot" from The Webster's II New Riverside Dictionary (Soukhanov *et al.*, Eds., 1988, The Riverside Publishing Co., Boston), pages 825 and 1015.

WEBSTER'S II
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used in the construction and repair of roads and runways.

The first of these is the *idea of a "good" or "bad" person*. This is a very common way of thinking about people, and it is often based on a single action or a single trait. For example, if someone is kind to others, we might call them a "good" person. If someone is cruel, we might call them a "bad" person. But this is a very simplistic way of looking at people. People are complex beings, and their actions and traits can change over time. A person who is kind today might become cruel tomorrow, and vice versa.

The second of these is the *idea of a "good" or "bad" action*. This is also a very common way of thinking about actions, and it is often based on a single action or a single trait. For example, if someone tells the truth, we might call that a "good" action. If someone lies, we might call that a "bad" action. But this is a very simplistic way of looking at actions. Actions are often influenced by many factors, and they can have different meanings in different contexts. A lie told to protect someone's feelings might be a "good" action, while a lie told to harm someone might be a "bad" action.

The third of these is the *idea of a "good" or "bad" situation*. This is a less common way of thinking about situations, but it is still used. For example, if someone is in a difficult situation, we might call that a "bad" situation. If someone is in an easy situation, we might call that a "good" situation. But this is a very simplistic way of looking at situations. Situations are often influenced by many factors, and they can have different meanings in different contexts. A difficult situation might be a "good" situation if it leads to personal growth, while an easy situation might be a "bad" situation if it leads to complacency.

In conclusion, the idea of "good" and "bad" is a very common way of thinking about people, actions, and situations. But it is a very simplistic way of looking at these things. People are complex beings, actions are often influenced by many factors, and situations are often influenced by many factors. We need to look at these things in a more nuanced way, taking into account all the factors that can influence them.

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